

120.400: X-RAYS IN THE HEALING ARTS

120.401: Purpose and Scope

105 CMR 120.400 establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with Commonwealth statutes to engage in the healing arts or veterinary medicine. The provisions of 105 CMR 120.400 are in addition to, and not in substitution for, other applicable provisions of 105 CMR 120.000.

120.402: Definitions

As used in 105 CMR 120.400, the following definitions apply:

Accessible Surface means the external surface of the enclosure or housing provided by the manufacturer.

Added Filtration means any filtration which is in addition to the inherent filtration.

Aluminum Equivalent means the thickness of type 1100 aluminum alloy¹ affording the same attenuation, under specified conditions, as the material in question.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

¹ The nominal chemical composition of type 1100 aluminum alloy is 99.00% minimum aluminum, 0.12% copper.

120.402: continued

Attenuation Block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy¹ or other materials having equivalent attenuation.

Automatic Exposure Control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also Phototimer).

Barrier (See Protective Barrier).

Beam Axis means a line from the source through the centers of the x-ray fields.

Beam-Limiting Device means a device which provides a means to restrict the dimensions of the x-ray field.

C-arm X-ray System means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

Cephalometric Device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified Components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

Certified System means any x-ray system which has one or more certified component(s).

Changeable Filters means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

Coefficient of Variation or C means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where

s = Estimated standard deviation of the population.

X = Mean value of observations in sample.

X_i = ith observation in sample.

n = Number of observations in sample.

Computed Tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Contact Therapy System means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five centimeters of the surface being treated.

Control Panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

¹ The nominal chemical composition of type 1100 aluminum alloy is 99.00% minimum aluminum, 0.12% copper.

120.402: continued

Contrast Scale (CS) means the change in the linear attenuation coefficient per CTN relative to water; that is:

$$CS = \frac{F_x - F_w}{(CTN)_x - (CTN)_w}$$

where:

F_x = linear attenuation coefficient of the material of interest

F_w = linear attenuation coefficient of water

$(CTN)_x$ = CTN of the material of interest

$(CTN)_w$ = CTN of water

Cooling Curve means the graphical relationship between heat units stored and cooling time.

CT means computed tomography; the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

CT Condition of Operation means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 105 CMR 120.400.

CT Gantry means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

CT Number (CTN) means the number used to represent the x-ray attenuation associated with each elemental area of the CT image, that is:

$$CTN = \frac{k (F_x - F_w)}{F_w}$$

where:

k = contrast (a value of 1,000 is assigned when the Hounsfield scale of CTN is used)

F_x = linear attenuation coefficient of the material of interest

F_w = linear attenuation of water

Dead-Man Switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector (See Radiation Detector).

Diagnostic Source Assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic X-ray System means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Diagnostic X-ray Imaging System means an assemblage of components for the generation, emission, and reception of x-ray and the transformation, storage, and visual display of the resultant x-ray image.

Direct Scattered Radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (*See Scattered Radiation*).

Elemental Area means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

Entrance Exposure Rate means the Exposure per unit time at the point where the center of the useful beam enters the patient.

Equipment (*See X-ray Equipment*).

Field Emission Equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to absorb preferentially selected radiations.

Fluoroscopic Imaging Assembly means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal Spot (Actual) means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General Purpose Radiographic X-ray System means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad Shield means a protective barrier for the testes or ovaries.

Half-value Layer means the thickness of specified material which attenuate the beam of radiation to an extent such that the Exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Healing Arts Screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized by the Commonwealth of Massachusetts to prescribe such x-ray tests for the purpose of diagnosis or treatment. to prescribe such x-ray tests for the purpose of diagnosis or treatment.

HVL (*See Half-value Layer*).

Image Intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image Receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Inherent Filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Irradiation means the exposure of matter to ionizing radiation.

120.402: continued

Kilovolts Peak (See Peak Tube Potential).

kV means kilovolts.

kVp (See Peak Tube Potential).

kWs means kilowatt second.

Lead Equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage Radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

- (1) The useful beam; and,
- (2) Radiation produced when the exposure switch or timer is not activated.

Leakage Technique Factors means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

- (1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs, *i.e.*, ten milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.
- (2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
- (3) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Linear Attenuation Coefficient (F) means the quotient of dN/N by $d1$ when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traveling a distance $d1$ in a specific material.

Light Field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage Regulation means the difference between the no- load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where

V_n = No-load line potential and

V_l = Load line potential.

mA means milliamperere.

mA.s means milliamperere second.

Maximum Line Current means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

Mobile X-ray Equipment (See X-ray Equipment).

Multiple Tomogram System means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Nominal Tomographic Section Thickness means the full-width at half-maximum of the sensitivity profile taken at the center of the cross sectional volume over which x-ray transmission data are collected.

NVLAP means National Voluntary Laboratory Accreditation Program.

Patient means an individual subjected to healing arts examination, diagnosis, or treatment.

Peak Tube Potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

Phototimer means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (*See Automatic Exposure Control*).

Portable X-Ray Equipment (*See X-ray Equipment*).

Position Indicating Device means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Positive Beam Limitation means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

Practitioner of the Healing Arts means an individual licensed to practice healing arts by the Commonwealth of Massachusetts.

Primary Protective Barrier (*See Protective Barrier*).

Protective Apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

Protective Barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- (1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam;
- (2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation.

Protective Glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Radiation Detector means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation Therapy Simulation System means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiographic Imaging System means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

120.402: continued

Rating means the operating limits as specified by the component manufacturer.

Recording means producing a permanent form of an image resulting from x-ray photons.

Reference Plane means a plane which is displaced from and parallel to the tomographic plane.

Routine means diagnostic procedures utilizing x-ray equipment that are performed at least weekly.

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomogram.

Scan Increment means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

Scan Sequence means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Scan Time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Scattered Radiation means radiation that, during passage through matter, has been deviated in direction (*See Direct Scattered Radiation*).

Secondary Dose Monitoring System means a system which will terminate irradiation in the event of failure of the primary system.

Secondary Protective Barrier (*See Protective Barrier*).

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID (*See Source-image Receptor Distance*).

Single Tomogram System means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

Source means the focal spot of the x-ray tube.

Source-image Receptor Distance means the distance from the source to the center of the input surface of the image receptor.

Spot Film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film Device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD means the distance between the source and the skin of the patient.

Stationary X-ray Equipment (*See X-ray Equipment*).

Stray Radiation means the sum of leakage and scattered radiation.

Technique Factors means the conditions of operation. They are specified as follows:

- (1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- (2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
- (3) For CT equipment designed for pulsed operations, peaktube potential in kV, scan time in seconds, and the number of x-ray pulses per scan or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
- (4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and,
- (5) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Termination of Irradiation means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Tomogram means the depiction of the x-ray attenuation properties of a section through the body.

Tomographic Plane means that geometric plane which is identified as corresponding to the output tomogram.

Tomographic Section means the volume of an object whose attenuation properties are imaged in a tomogram.

Tube means an x-ray tube, unless otherwise specified.

Tube Housing Assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube Rating Chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful Beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Variable-aperture Beam-limiting Device means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible Area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray Exposure Control means a device, switch, button, or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

X-ray Control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimer, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray Equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

- (1) "Mobile X-ray Equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
- (2) "Portable X-ray Equipment" means x-ray equipment designed to be hand-carried.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

(3) "Stationary X-ray Equipment" means x-ray equipment which is installed in a fixed location.

120.402: continued

X-Ray Field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the Exposure rate is $\frac{1}{4}$ of the maximum in the intersection.

X-ray High-voltage Generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high voltage switches, electrical protective devices, and other appropriate elements.

X-ray System means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray Table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or buckey), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

X-Ray Tube means any electron tube which is designed to be used primarily for the production of x-rays.

120.403: General Requirements

(A) Administrative Controls.

(1) Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of 105 CMR 120.403(A)(1) are met in the operation of the x-ray system(s).

(a) An x-ray system which does not meet the provisions of 105 CMR 120.400 shall not be operated for diagnostic or therapeutic purposes, if so directed by the Radiation Control Program.

(b) Individuals who shall be operating the x-ray systems shall meet the requirements of 105 CMR 125.000: *Licensing of Radiologic Technologists*.

(c) A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for routine examinations performed with that system, the following information:

1. Patient's body size and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;
2. Type and size of the film or film-screen combination to be used;
3. Type and focal distance of the grid to be used, if any;
4. Source to image receptor distance to be used (except for dental intra-oral radiography); and,
5. Type and location of placement of patient shielding (*e.g.* gonad, *etc.*) to be used.

(d) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(e) Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, and parents of pediatric patients whose presence might be required for the medical procedure or training shall be in the room or area during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
2. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.
- (f) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
- (g) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
 1. Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and,
 2. exposure of an individual for the purpose of healing arts screening except as authorized by 105 CMR 120.403(A)(1)(k).
- (h) When a patient or film must be provided with auxiliary support during a radiation exposure:
 1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 105 CMR 120.403(A)(1)(d), shall list individual projections, specific patient conditions, or psychological development level where holding devices cannot be utilized;
 2. Written safety procedures, as required by 105 CMR 120.403(A)(1)(d), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
 3. The human holder shall be protected as required by 105 CMR 120.403(A)(1)(e);
 4. No individual shall be used routinely to hold film or patients;
 5. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and,
 6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.
- (i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.
 1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.
 2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
 3. Protective equipment including aprons, gloves, and shields shall be checked annually for defects, such as holes, cracks, and tears to assure reliability and integrity. A record of this test shall be maintained for inspection by the Radiation Control Program. If such defect is found, equipment shall be replaced or removed from service until repaired or replaced.
 4. Radiographic systems other than fluoroscopic, dental intra-oral, or veterinarian systems shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.
 5. Mammographic procedures shall only be performed on special purpose mammographic equipment.
 6. Mobile or portable radiographic systems shall only be used for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation
 7. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:
 - a. Be positioned properly, *i.e.*, tube facing the right direction, and grid centered to the central ray;

105 CMR: DEPARTMENT OF PUBLIC HEALTH

- b. If of the focus type, be of the proper focal distance for the SIDs being used.

(j) All occupationally exposed individuals are subject to the requirements of 105 CMR 120.211, 120.215, 120.217 and 120.218.

(k) Healing Arts Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Radiation Control Program. When requesting such approval, that person shall submit the information outlined in 105 CMR 120.421: *Appendix B*. If any information submitted to the Radiation Control Program becomes invalid or outdated, the Radiation Control Program shall be immediately notified.

(l) If the facility ceases to operate, the facility must notify the Radiation Control Program within 15 days. Included in this notification, is the name and address of the person who disposed of the x-ray unit.

(2) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Radiation Control Program:

(a) Model and serial numbers of all major components, and user's manuals for those components;

(b) Records of installation, surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after the effective date of 105 CMR 120.000 with the names of persons who performed such services;

A copy of the service providers certificate of registration shall be maintained by the facility.

(c) A scale drawing provided by a qualified expert of the room in which a stationary x-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

1. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or,

2. The type and thickness of materials, or lead equivalency, of each protective barrier; and,

(d) A copy of all correspondence with this Radiation Control Program regarding that x-ray system.

(3) X-ray Utilization Log. Except for veterinary facilities, each facility shall maintain an x-ray record containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

(4) Radiograph and Record Retention. Radiographs shall be retained for at least a minimum of five years following last visit of the patient. The written reports become a part of the patient's medical record and are to be retained for 30 years following last visit of patient.

(B) Plan Review.

(1) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Radiation Control Program for review and approval. The required information is denoted in 105 CMR 120.420: *Appendix A* and 120.422: *Appendix B*, unless specifically exempted.

(2) The Radiation Control Program may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 105 CMR 120.211, 120.217, 120.218 and 120.221.

(C) X-ray Film Processing Facilities and Practices.

(1) Each installation using a radiographic x-ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

120.403: continued

(a) Manually developed film:

1. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and
2. The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8
16.1	61	8½
15.6	60	9½

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(b) Automatic processors and other closed processing systems:

- (1) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time ^{a/}
°C	°F	Seconds
35.5	96	19
35.0	95	20
34.5	94	21
34.0	93	22
33.5	92	23
33.0	91	24
32.0	90	25
31.5	89	26
31.0	88	27
30.5	87	28
30.0	86	29
29.5	85	30
^{a/} Immersion time only, no crossover time included.		

2. The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.
- (c) Processing deviations from the requirements of 105 CMR 120.403(C)(1) shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (*e.g.*, extended processing, and special rapid chemistry). The requirements of 105 CMR 120.403(C)(1)(c) apply only to film processors routinely used in processing diagnostic x-ray images.
- (d) Quality Assurance tests for the processor shall be performed on days being used.
- (e) Test tools for quality assurance tests for the processor shall include the following:
 1. Densitometer
 2. Sensitometer
 3. Thermometer
 4. Film
- (f) Daily film processor quality assurance tests shall include: Checking solution temperatures.
 1. The developer temperature shall be as recommended by the film manufacturer.
 2. Mercury thermometers are prohibited for determining solution temperatures.
- (g) Determination and recording of the speed step. Maximum control limits shall not exceed ± 0.15 optical density (OD).
- (h) Calculation and recording of the contrast index or density difference. Maximum control limits shall not exceed ± 0.15 optical density (OD).
- (i) Measuring and plotting the Base + Fog. Maximum base plus fog density shall not exceed 0.25 optical density (OD).
- (j) Chemistry replenishment rates shall be measured and recorded semi-annually.
- (k) Processor sensitometric tests results including speed index, contrast index, and base plus fog shall be plotted on control charts.
- (l) Operating levels and control limits for processor quality assurance tests shall be indicated on the control chart.
- (m) Quality assurance records shall be maintained for a minimum of 24 months and readily available for review by representatives of the Department.
- (2) Other Requirements:
 - (a) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

120.403: continued

(b) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

1. Quality assurance tests for darkroom integrity shall be performed at least semi-annually.
2. Each facility shall use pre-exposed film for performing quality assurance tests.
3. No smoking or eating is permitted in the darkroom.
4. The darkroom shall be kept free of dust.
5. Counter tops, floors, and processing feed trays shall be cleaned daily before any films are handled or processed.

(c) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(d) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(e) Film cassettes and intensifying screens shall be kept free of artifacts and shall be cleaned regularly and replaced as necessary to best assure radiographs of good diagnostic quality.

Screens shall be cleaned at intervals not to exceed one month with a screen cleaner recommended by the screen manufacturer. A copy of this requirement shall be kept in the darkroom.

(f) Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

(g) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

120.404: General Requirements for All Diagnostic X-ray Systems

In addition to other requirements of 105 CMR 120.400, all diagnostic x-ray systems shall meet the following requirements:

(A) Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(B) Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(C) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgen (25.8 FC/kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(D) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgen (0.516 FC/kg) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

120.404: continued

(E) Beam Quality.(1) Half-value Layer.

(a) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

(b) For capacitor energy storage equipment, compliance with the requirements of 105 CMR 120.404(E) shall be determined with the system fully charged and a setting of ten mAs for each exposure.

(c) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

(2) Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 105 CMR 120.404(E)(1) is in the useful beam for the given kVp which has been selected.

TABLE I			
Design Operating Range	Measured Potential (kVp)	Half-Value Layer In mm Aluminum	
		Dental Intra-Oral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980	All Other Diagnostic X-Ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(F) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

(G) Mechanical Support of Tube Housing Assembly. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

(H) Technique Indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic Exposure controls are used, the technique factors which

105 CMR: DEPARTMENT OF PUBLIC HEALTH
are set prior to the exposure shall be indicated.

120.404: continued

(2) The requirement of 105 CMR 120.404(H)(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(I) Maintaining Compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

(J) Locks. All positioning locking, holding, and centering devices on x-ray systems components and systems shall function as intended.

120.405: Fluoroscopic X-ray Systems

Fluoroscopic X-ray Systems shall be installed and maintained to comply with the Federal Performance Standard for Fluoroscopic Equipment, 21 CFR 1020.32 and shall also meet the following requirements except 21 CFR 1020.32 shall prevail should there be a conflict.

(A) Limitation of Useful Beam.

(1) Primary Barrier.

- (a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.
- (b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic Beam Limitation.

- (a) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3% of the SID. The sum of the excess length and the excess width shall be no greater than 4% of the SID.
- (b) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.
- (c) For uncertified fluoroscopic systems without a spot film device, the requirements of 120.405(A)(2)(a) apply.
 - 1. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;
 - 2. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;
 - 3. If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;
 - 4. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and,
 - 5. For non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film Beam limitation. Spot-film devices shall meet the following requirements:

- (a) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be

105 CMR: DEPARTMENT OF PUBLIC HEALTH

automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

- (b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4% of the SID;
 - (c) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters by five centimeters;
 - (d) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2% of the SID; and,
 - (e) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- (4) Override. If a means exists to override any of the automatic x-ray field size adjustments required in 105 CMR 120.405(A)(2), that means:
- (a) Shall be designed for use only in the event of system failure;
 - (b) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and,
 - (c) Shall be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

(B) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(C) Exposure Rate Limits.

(1) Entrance Exposure Rate Allowable Limits.

- (a) Fluoroscopic equipment which is provided with automatic Exposure rate control shall not be operable at any combination of tube potential and current which will result in an Exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:
 - 1. During recording of fluoroscopic images; or,
 - 2. When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an Exposure rate in excess of five roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (b) Fluoroscopic equipment which is not provided with automatic Exposure rate control shall not be operable at any combination of tube potential and current which will result in a Exposure rate in excess of 1.3 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient, except:
 - 1. During recording of fluoroscopic images; or
 - 2. When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (c) Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 2.6 mC/kg (ten roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except:
 - 1. During recording of fluoroscopic images; or

2. When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 1.3 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient, unless high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (d) Any fluoroscopic equipment manufactured after May 19 1995 which can exceed 1.3 mC/kg (five roentgens) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 2.6 mC/kg (ten roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when high level control is activated.
- (e) Compliance with the requirements of 105 CMR 120.405(C) shall be determined as follows:
 1. If the source is below the table, Exposure rate shall be measured one centimeter above the tabletop or cradle.
 2. If the source is above the table, the Exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
 3. For a C-arm type of fluoroscope, the Exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;
 4. For a lateral type fluoroscope, the Exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.
- (f) Periodic measurement of maximum entrance Exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:
 1. Such measurements shall be made annually or after any maintenance of the system which might affect the Exposure rate;
 2. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 105 CMR 120.403(A)(2)(b). The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;
 3. Conditions of periodic measurement of typical entrance Exposure rate are as follows:
 - (a) The measurement shall be made under the conditions that satisfy the requirements of 105 CMR 120.405(C)(1)(c);
 - (b) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;
 - (c) The x-ray system that incorporates automatic Exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of 105 CMR 120.405(C)(1)(d)3.; and,
 4. Conditions of periodic measurement of maximum entrance Exposure rate are as follows:
 - (a) The measurement shall be made under the conditions that satisfy the requirements of 105 CMR 120.405(C)(1)(c);
 - (b) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance Exposure rate;
 - (c) The x-ray system(s) that incorporates automatic Exposure rate control shall have sufficient attenuative material placed in the useful beam to

105 CMR: DEPARTMENT OF PUBLIC HEALTH
produce the maximum entrance exposure rate of the system.

(D) Barrier Transmitted Radiation Rate Limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgen (0.516 FC/kg) per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance Exposure rate.

(2) Measuring Compliance of Barrier Transmission.

(a) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(b) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(c) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

(d) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(e) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(E) Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

(F) Source-to-skin Distance. The SSD shall not be less than:

- (1) 38 centimeters on stationary fluoroscopes manufactured on or after August 1, 1974;
- (2) 35.5 centimeters on stationary fluoroscopes manufactured prior to August 1, 1974;
- (3) 30 centimeters on all mobile fluoroscopes; and,
- (4) 20 centimeters for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be taken during the use of this type of fluoroscope.

(G) Fluoroscopic Timer.

(1) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(H) Control of Scattered Radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(a) Is at least 120 centimeters from the center of the useful beam; or

(b) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 105 CMR 120.403(A)(1)(e).

(3) The Agency may grant exemptions to 105 CMR 120.405(H)(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption. See 105 CMR 120.423: *Appendix D* for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

120.405: continued

(I) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 105 CMR 120.405(A), (C), (D) and (G) provided that:

- (1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and,
- (2) Systems which do not meet the requirements of 105 CMR 120.405(G) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(J) Spot film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) modes shall meet the exposure reproducibility requirements when operating in the spot film mode.

(K) Operator Qualifications.

- (1) A facility shall ensure that only a licensed physician or a radiologic technologist who is trained in the safe use of fluoroscopic x-ray systems licensed in accordance with 105 CMR 125.000 shall be allowed to operate these systems. All persons using fluoroscopic x-ray systems shall have, at a minimum, documented training in the topics specified 105 CMR 120.405(K)(2).
- (2) Training to meet requirements of 105 CMR 120.405(K)(1) shall include, but not be limited to the following:
 - (a) Principles and operation of the fluoroscopic x-ray system;
 - (b) Biological effects of x-ray;
 - (c) Principles of radiation protection;
 - (d) Fluoroscopic outputs;
 - (e) High level control options;
 - (f) Dose reduction techniques for fluoroscopic x-ray systems; and
 - (g) Application requirements of 105 CMR 120.000.
- (3) The facility shall maintain all records relating to compliance with the training requirements for five years.
- (4) The facility shall establish policies and procedures for restricting the use of fluoroscopic systems to only those physicians who have been granted privileges for the use of fluoroscopy based on a determination of adequate training and knowledge of the curriculum of 105 CMR 120.405(K)(2).
- (5) The facility shall ensure that all non-radiologist physician using fluoroscopy equipment obtain annual training in Radiation Safety/Radiation Protection and maintain all records relating to compliance with this training requirement for five years.

(L) Patient Dose Evaluation.

- (1) Each facility performing fluoroscopically-guided interventional procedures shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury as further defined in 105 CMR 120.405(L)(5).
- (2) Records documenting that policies and procedures have been developed to determine that those procedures that have a potential to result in patient doses exceeding the threshold for injury have been established to reduce the probability of such exposures and that appropriate action occurs for patients receiving doses that warrant follow-up.
- (3) The facility shall have a patient dose monitoring procedures in place. When the fluoroscopy unit is equipped with an Air-Kerma dose readout, the recording of this value shall suffice as a patient dose record.
- (4) The facility shall document in the patient's medical record an estimate of the absorbed dose to the skin.
- (5) Any cumulative absorbed dose to the skin equal to or greater than 1 Gy (100 rads) shall be noted in the patients medical record and reviewed by the Radiation Safety Committee.
- (6) Each facility that use fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name. The record shall be maintained for five years.

120.405: continued

(M) Equipment Operation.

- (1) Radiological technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or a licensed Radiological Technologist.
- (2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

120.406: Radiographic Systems Other Than Fluoroscopic, Computed Tomography Systems

(A) Beam Limitation Except for Mammographic Systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 105 CMR 120.406(G)(2) has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

(1) General Purpose Stationary and Mobile X-ray Systems, Including Veterinary Systems (Other than Portable) Installed After December 31, 1997.

- (a) Only x-ray systems provided with a means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used;
- (b) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam;
- (c) The Agency may grant an exemption on non-certified x-ray systems to 105 CMR 120.406(A)(1)(a); and,
- (d) Provided the registrant makes a written application for such exemption and in that application:
 1. Demonstrates it is impractical to comply with 105 CMR 120.406(A)(1)(a) and (b); and,
 2. The purpose of 105 CMR 120.406(A)(1)(a) and (b) will be met by other methods.

(2) Additional Requirements for Stationary General Purpose X-ray Systems. In addition to the requirements of 105 CMR 120.406, all stationary general purpose x-ray systems, both certified and non-certified shall meet the following requirements:

- (a) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within 2%;
- (b) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and,
- (c) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Radiographic Systems Other Than Those Designated in 105 CMR 120.406(A)(1) through (3).

- (a) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

(c) 105 CMR 120.406(A)(4)(a) and (b) may be met with a system that meets the requirements for a general purpose x-ray system as specified in 105 CMR 120.406(A)(1) or, when alignment means are also provided, may be met with either:

1. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or,
2. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(B) Radiation Exposure Control

(1) Timers. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a foot pedal. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Exposure Termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(a) Manual Exposure Control.

An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

1. Exposure of ½ second or less; or,
2. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(b) Automatic Exposure Controls. When an automatic Exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;
2. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
3. The minimum exposure time for all equipment other than that specified in 105 CMR 120.406(B)(3)(b)2. shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;
4. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and,
5. A visible signal shall indicate when an exposure has been terminated at the limits required by 105 CMR 120.406(B)(3)(b)4., and manual resetting shall be required before further automatically timed exposures can be made.

(4) Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of $C\ kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \neq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average $C \text{ kg}^{-1} \text{ s}^{-1}$ (mR/s) values.

(5) Exposure Control Location. The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

(6) Operator Protection, Except Veterinary Systems.

(a) Stationary Systems. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

(b) Mobile and Portable Systems. Mobile and portable x-ray systems which are:

1. Used continuously for greater than one week in the same location, *i.e.*, a room or suite, shall meet the requirements of 105 CMR 120.406(B)(6)(a);

2. Used for less than one week at the same location shall be provided with either a protective barrier at least 6.5 feet (two m) high for operator protection during exposure, or means shall be provided to allow the operator to be at least nine feet (2.7 m) from the tube housing assembly during the exposure.

3. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(7) Exposure Reproducibility. When all techniques factors are held constant, including control panel selections associated with exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

(C) Source-to-skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

(D) Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgen (0.516 FC/kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(E) Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value for kVp and 20% for time.

(F) mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated:

(1) Equipment Having Independent Selection of X-ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliamperere-seconds product ($C \text{ kg}^{-1} \text{ mAs}^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

(2) Equipment Having a Combined X-ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of $C \text{ kg}^{-1} \text{ mAs}^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

(3) Measuring Compliance. Determination of compliance shall be based on three exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(G) Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Beam Limitation for Portable X-ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 105 CMR 120.406(A)(1).

(2) Field Limitation and Alignment on Stationary General Purpose X-ray Systems. For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(C):

(a) Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five seconds or is manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.

(b) The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than 3% of the SID and that the sum of the length and width differences without regard to sign be no greater than 4% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

(c) The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than five by five centimeters. Return to positive beam limitation as specified in 105 CMR 120.406(F)(6)(a) and (b) shall occur upon a change in image receptor.

(d) Positive beam limitation may be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or when either the beam axis or table angulation is not within 10E of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.

(e) A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode. It shall be impossible to remove the key while the positive mode is overridden.

(3) Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(4) Transmission Limit for Image Receptor Supporting Devices Used for Mammography. For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the Exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 C/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(A) General Requirements.

- (1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
- (2) Reproducibility. With a timer setting of 0.3 second or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{\max}) minus the minimum exposure period (T_{\min}) when 4 timer tests are performed:

$$T \geq 5(T_{\max} - T_{\min})$$

(3) X-ray Control.

- (a) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.
- (b) The exposure switch shall be of the dead-man type.
- (c) Each x-ray control shall be located in such a way as to permit the operator to remain in an area of less than two millirems in any one hour during the entire exposure.
- (4) Exposure Reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four Exposures are made at identical technique factors, the value of the average Exposure (E) is greater than or equal to five times the maximum Exposure (E_{\max}) minus the minimum Exposure (E_{\min}):

$$E \geq 5(E_{\max} - E_{\min})$$

(B) Additional Requirements for Dental Intraoral Systems.

- (1) Source-to-skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD to not less than:
 - (a) 18 centimeters if operable above 50 kVp; or,
 - (b) ten centimeters if not operable above 50 kVp.
- (2) Field Limitation.
 - (a) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters.
 - (b) An open-ended beam-indicating device shall be used.

(C) Additional Requirements for Dental Extraoral System Field Limitation.

- (1) Dental rotational panoramic systems shall be provided with means to limit the x-ray beam to the imaging slit in the transverse axis and shall not exceed a total of 0.5 inch larger than the imaging slit in the vertical axis.
- (2) All other dental extraoral radiographic systems (e.g., cephalometric) shall be provided with means to both size and align the x-ray field so that it does not exceed beyond any edge of the image receptor by more than 2% of the SID.

(D) Additional Requirements Applicable to Certified Systems Only. Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

- (1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation Exposure shall be no greater than 0.05, for any specific combination of selected technique factors.
- (2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100% of the maximum rating, the average ratios of Exposure to the indicated milliamperere-seconds product obtained at any 2% consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \neq 0.10 (X_1 + X_2)$$

where: X_1 and X_2 are the average mR/mAs values obtained at each of two consecutive tube current settings.

120.407: continued

- (3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
- (4) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".
- (5) Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of 105 CMR 120.404(E)(1).

(E) Additional Operation Controls for Dental Radiographic Systems.

- (1) Film holding devices shall be used except in individual cases in which the practitioner has determined that such holding are contraindicated. Written safety procedures required by 105 CMR 120.400 shall state the criteria under which the exception shall apply.
- (2) The tube housing support shall be constructed and adjusted so that the tube housing shall not drift from its set position during an exposure. Neither the tube housing nor the support housing shall be hand-held during an exposure.
- (3) The operator shall stand at least six feet from the useful beam or behind a protective barrier. Where a protective barrier is utilized, a viewing system shall be used.
- (4) Individuals who operate only dental radiographic systems are exempt from the personnel monitoring requirements of 105 CMR 120.211.

120.408: Veterinary X-ray Systems(A) Equipment.(1) Technique and Exposure Indicators.

- (a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.
- (b) The requirements of 105 CMR 120.408(A)(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.
- (c) The x-ray control shall provide visual indication of the production of x-rays observable at or from the operator's protected position whenever x-rays are produced.
- (2) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgen in one hour when the x-ray tube is operated at its leakage technique factors. Measurement is averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (3) The useful beam shall be restricted to the area of clinical interest and no larger than the size of the image receptor.
- (4) Collimating devices shall be provided and shall limit the beam to the area of the image receptor to within 2% of the SID, and shall provide the same degree of protection as is required of the housing.
- (5) The half-value layer of the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters and 70 kVp, and two millimeters aluminum equivalent for machines operating above 70 kVp.
- (6) A device shall be provided to terminate the exposure after a preset time or Exposure.
- (7) A dead-man type of exposure switch shall be provided, together with an exposure cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures.
- (8) The coefficient of variation of Exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four Exposures are made at identical technique factors, the value of the average Exposure (E) is greater than or equal to five times the maximum Exposure (E_{\max}) minus the minimum Exposure (E_{\min}):

$$E \geq 5 (E_{\max} - E_{\min})$$

- (9) The primary beam shall be aligned with the film by using specified techniques in the facility's operating procedures.

120.408: continued

(10) Fluoroscopic, CT, and therapy systems used in veterinary facilities shall meet the requirements of 105 CMR 120.405, 120.409 and 120.410 respectively, except the aural communications of 105 CMR 120.400, 120.422: *Appendix C*, 120.409(B)(1) and 120.410(B)(1).

(11) Portable machines shall be used in a manner which complies with 105 CMR 120.000.

(B) Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 105 CMR 120.211, 120.221 and 120.222.

(C) Additional Operational Controls for Veterinary Facilities.

- (1) All exams and retakes shall be ordered by the veterinarian.
- (2) The x-ray tube shall not be held by any individual during radiographic exposures.
- (3) Unless required to restrain an animal, the operator shall stand at least six feet away from the useful beam and the animal during radiographic exposures.
- (4) No individual, other than the operator, shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required.
- (5) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be used when technique permits.
- (6) A pregnant female shall not hold or restrain an animal.

120.409: Computed Tomography X-ray Systems

(A) Equipment Requirements.

(1) Tomographic Plane Indication and Alignment.

- (a) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.
- (b) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane offset from the tomographic plane. The reference plane can be offset from the location of the tomographic planes.
- (c) If a device using a light source is used to satisfy 105 CMR 120.409(A)(1)(a) or (b), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(2) Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(3) Initiation of Operation.

- (a) The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
- (b) Means shall be provided to require operator initiation of each individual scan or series of scans.
- (c) All emergency buttons/switches shall be clearly labeled as to their functions.

(4) Termination of Exposure.

- (a) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices which monitor equipment function.
- (b) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 105 CMR 120.409(A)(4)(a).
- (c) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than 0.5 second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.

120.409: continued

(5) Extraneous Radiation. The system shall perform such that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time that scans are not being performed does not exceed the levels permitted by 105 CMR 120.404(C).

(6) Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured after September 3, 1985.

(a) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.

(b) If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 seconds. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(c) The deviation of indicated scan increment versus actual increment shall not exceed to within one millimeter with any mass from zero to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

(B) Facility Design Requirements.

(1) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing System.

(a) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(b) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

(C) Dose Measurements and Spot Checks.

(1) Dose Measurements.

(a) Dose measurements of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert.

(b) Dose measurements of a CT x-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of a qualified expert, could cause a change in the radiation output.

(c) Measurements of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated or inter compared with a calibrated chamber within the preceding two years. The calibration of such system shall be traceable to a national standard.

(d) Calibration procedures shall be in writing. Records of calibration performed shall be maintained for inspection by the Radiation Control Program.

(2) Spot Checks.

(a) Spot check procedures shall be developed by a qualified expert.

(b) All spot checks shall be included in the calibration required by 105 CMR 120.409(C)(1), and otherwise at time intervals and system conditions specified by a qualified expert.

(c) Spot checks shall include acquisition of images obtained with the phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by 105 CMR 120.409(C)(1). The images shall be retained until a new dose measurement is performed in two forms as follow:

1. Photographic copies of the images obtained from the image display device; and
2. Images stored in digital form of the most recent spot check on a storage medium compatible with the CT x-ray system.

(D) Additional Operational Controls for CT X-Ray Systems.

(1) The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation and who holds a valid Massachusetts license in radiologic technology.

120.409: continued

- (2) Information shall be available at the control panel or in a specified location regarding the operation and calibration of the system. The information shall contain:
- (a) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;
 - (b) The results of at least the most recent checks conducted on the system; and,
 - (c) The distance, in millimeters, between the tomographic plane and the reference plane, if a reference plane is utilized.

120.420: Appendix A -- Radiation Shielding and Safety Requirements

In order for the Radiation Control Program to provide an evaluation, and official approval on shielding requirements for a radiation installation, the following must be submitted. The plans shall show as a minimum the following:

- (A) The normal location of the x-ray system's radiation port, the port's travel and transverse limits, general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth and the location of the x-ray control panel.
- (B) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor and ceiling of the room(s) concerned.
- (C) The dimensions of the room(s) concerned.
- (D) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is any exterior wall, show distance to the closest area(s) where it is likely that individuals will be present.
- (E) The make and model of the x-ray equipment.
- (F) The typical type of examination(s) and treatment(s) which will be performed with the equipment.
- (G) Information on the anticipated workload of the x-ray system(s).
- (H) An interlock and/or warning light shall be installed at all egresses. For diagnostic x-ray installations, the warning light shall be wired to the rotor of the x-ray system.
- (I) All basic assumptions used to determine the shielding requirements in developing these plans shall be submitted with these plans.

120.421: Appendix B -- Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

- (A) Name and address of the applicant and, where applicable, the names and addresses of agents within this Commonwealth.
- (B) Diseases or conditions for which the x-ray examinations are to be used in diagnoses.
- (C) A detailed description of the x-ray examinations proposed in the screening program.
- (D) Description of the population to be examined in the screening program, *i.e.*, age, sex, physical condition, and other appropriate information.
- (E) An evaluation of any known alternate methods not involving ionizing radiation, which would achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.

120.421: continued

- (F) An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of 105 CMR 120.000.
- (G) A description of the diagnostic film quality control program.
- (H) A copy of the technique charts for the x-ray examination procedures to be used.
- (I) The qualifications of each individual who will be operating the x-ray system(s).
- (J) The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
- (K) The name and address of the individual who will interpret the radiograph(s).

120.422: Appendix C -- Design Requirements for an Operator's Booth

- (A) Space Requirements
 - (1) The operator shall be allotted not less than 7.5 square feet (0.697 m²) of unobstructed floor space in the booth.
 - (2) The operator's booth may be any geometric configuration with no dimension of less than two feet (0.61 m).
 - (3) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables or other similar encroachments.
 - (4) The booth shall be located or constructed such that unattenuated direct scatter radiation originating in the examination table or at the wall cassette shall not reach the operator's station in the booth.
- (B) Structural Requirements
 - (1) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high.
 - (2) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
 - (3) Shielding shall be provided to maintain exposure inside the booth equal to or less than two mR per week.
- (C) X-ray Control Placement. The x-ray exposure switch for the system shall be fixed within the booth and;
 - (1) Shall be at least 40 inches (1.02 m) from any open edge of the booth and;
 - (2) Shall allow the operator to use the majority of the available viewing windows.
- (D) Viewing System Requirements.
 - (1) Each booth shall have at least one viewing device which will:
 - (a) Be so placed that the operator can view the patient during any exposure; and,
 - (b) The device should be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure, which will prevent the exposure if the door is not closed.
 - (2) When the viewing system is a window, the following requirements also apply:
 - (a) The viewing area shall be at least one square foot (0.0929 m²).
 - (b) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457m) from the edge of the booth.
 - (c) The material constituting the window shall have at least the same lead equivalence as that required in the booth's walls in which it is mounted.
 - (3) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 105 CMR 120.421: *Appendix C(A)(4)*.

120.422: continued

- (4) When the viewing system is by electronic means:
 - (a) The camera shall be so located as to accomplish the general requirements of 105 CMR 120.421: *Appendix C(A)(4)*; and,
 - (b) There shall be an alternate viewing system as a backup for the primary system.
 - (c) Means shall be provided for the operator to be able to orally communicate with the patient at all times.

120.423: Appendix D --Exemptions From Shielding for Certain Fluoroscopic Procedures

- (A) Angiograms
- (B) Arthrograms
- (C) Biliary drainage procedures
- (D) Fluoroscopic biopsy procedures
- (E) Myelograms
- (F) Percutaneous cholangiograms
- (G) Percutaneous nephrostomies
- (H) Sinograms or fistulograms
- (I) T-tube cholangiograms